

S/N 09/970,146

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Eric G. ~~DEPARTMENT~~

Examiner: Kennedy Schaetzle

Serial No.: 09/970,146

Group Art Unit: 3766

Filed: October 2, 2001

Docket: 279.262US1

Title: MEDICAL DEVICE HAVING RHEOMETRIC MATERIALS AND METHOD THEREFOR

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Applicant respectfully requests review of the final rejection provided in the Final Office Action dated October 5, 2005 and maintained in the Advisory Action dated January 9, 2006. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated below:

- I. Applicant respectfully submits there is a clear deficiency in the prima facie case in support of the § 102 rejections.
- II. Applicant respectfully submits there is a clear deficiency in the prima facie case in support of the § 103 rejections.

Applicant requests review of both sets of rejections and separate decisions on each.

§102 Rejections of the Claims

Claims 1 and 3-8 were rejected under § 102(e) in view of Maseda. Applicant traverses these rejections. Applicant submits the rejections of claims 1, 3- 8 fail because all of the elements are not identically shown in the cited reference. Applicant cannot find in Maseda, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Claims 3-8 depend from claim 1 and thereby include all of its limitations. Further, Applicant cannot find in Maseda, the device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7.

Applicant submits the Final Office Action refuses to give patentable weight to a functional limitation recited in claim 1, such as, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue. Pursuant to M.P.E.P. § 2173.05(g), “[a] functional limitation *must be evaluated and considered*, just like any other limitation of the claim.” (Emphasis added). Because patentable weight is given to functional limitations, Applicant submits that Maseda fails to identically show the claimed invention in as complete detail, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from

tissue, as recited in claim 1, and incorporated in claims 3-8. The Final Office Action attempts to address the deficiency of Maseda at page 2, section 3, "the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode . . . Platinum is considered to be capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature." The Advisory Action similarly states, "[t]he electrode disclosed in the prior art reference is substantially equivalent to that disclosed by applicant and capable of operating in the manner claimed." Applicant traverses these statements in so far as they fail to properly characterize the teaching of Maseda. Applicant can not find in Maseda, for instance, at least one electrode configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. In contrast, the only reference in Maseda to an electrode states:

Ion-exchange polymer-noble metal composites are manufactured utilizing a chemical process in which a noble metal is deposited within the molecular network of the base ionic polymer. Metal ions, for example, platinum are dispersed throughout the hydrophilic regions of the polymer and subsequently chemically reduced to the corresponding metal atoms. This process results in the formation of dendritic-type electrodes. When an external voltage of approximately 2 volts or higher is applied to an ion-exchange polymer-noble metal composite film, it bends toward the anode. An increase in the applied voltage, up to a predetermined limit, causes a larger bending displacement. When the polarity of the voltage is changed, the film undergoes a swinging movement. The displacement of the film not only depends on the magnitude of the applied voltage, but also on the frequency of the applied voltage. Lower frequencies lead to higher displacements. Accordingly, the movement of the film or strip may be fully controllable by controlling the applied voltage.

Maseda, column 5, lines 1-19. Applicant respectfully submits the preceding quotation is the only teaching for an electrode in Maseda and does not appear to teach the *identical invention in as complete detail as* is contained in claim 1, and required by M.P.E.P. § 2131.

Further, Applicant respectfully traverses the Final Office Action statement at page 5, first paragraph, "Platinum electrodes are *inherently* capable of transmitting and receiving electrical signals to and from the body due to their conductive and biocompatible nature." (Emphasis added). To serve as an anticipation when a reference is silent about the asserted inherent characteristic, the gap in the reference may be filled with recourse to extrinsic evidence. But, such evidence must make clear that "the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). (Emphasis added). Applicant submits that the Final Office Action has not produced extrinsic evidence to show that at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1 is *necessarily* present in Maseda. Further, the Final Office Action has not provided a *prima facie* showing of technical reasoning to support the conclusion at page 5, first paragraph

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of the Final Office Action, as required by M.P.E.P. § 2112.fn1 Instead, the Final Office Action only argues that “the platinum electrode of Maseda *can* be attached to the outer tubular body 114 enabling it to come into contact with tissue or conductive body fluids.” (Emphasis Added). Final Office Action, page 5, first paragraph. Moreover, because there is no teaching in Maseda supporting the electrode modification described by this Final Office Action statement, Applicant respectfully submits the statement appears to blur the line between anticipation and obviousness. To the extent this statement is directed toward an obviousness rejection, according to MPEP § 2143.01, the mere fact that references *can* be combined or modified does not render the resultant modification obvious unless the prior art also suggests the desirability of the modification. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).fn2 Applicant respectfully submits an objective suggestion to modify Maseda in the proposed manner has not been provided in either the Final Office Action or the Advisory Action and therefore submits a proper *prima facie* case of obviousness has not been provided.

§103 Rejections of the Claims

Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 were rejected under § 103(a) over Lieber et al. in view of Maseda. Applicant traverses the rejections. Applicant submits the proposed combination of Maseda with Lieber would change the principle of operation of Lieber and therefore the proposed combination is insufficient to render the claims *prima facie* obvious as stated in MPEP § 2143.01.fn3 The Lieber mechanism includes a balloon-tipped catheter having an inflated balloon that is propelled by blood flow from the right atrium into the pulmonary artery to traverse the vasculature (See Lieber, column 3, lines 52-64). In contrast, Maseda teaches the use of electroactive polymer strands to navigate the vasculature (See Maseda, abstract). By exchanging the inflated balloon mechanism of Lieber with the electroactive polymer actuators of Maseda the principle of operation for navigating the vasculature of Lieber is changed, and the proposed combination is thereby insufficient to render claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 *prima facie* obvious.

Further, Lieber teaches away from the proposed combination described in the Final Office Action and the Final Office Action therefore does not maintain a proper motivation to combine Lieber with Maseda. Lieber teaches away from the proposed combination because Lieber advises using an entirely different mechanism having a different principle of operation to traverse the vasculature from Maseda and therefore does not need the

1 “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” MPEP § 2112 quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

2 Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device “may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.” 916 F.2d at 682, 16 USPQ2d at 1432.

3 If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. See MPEP § 2143.01 quoting *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

teaching of Maseda. The Lieber mechanism uses an inflated balloon that is propelled by blood flow to traverse the vasculature (See Lieber, column 3, lines 52-64), as opposed to an alternate mechanism having at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited in claims 9 and 23. Claims 10, 12-14, 16, 21, 22 and 58 depend from claim 9 and thereby include all of its limitations. Claim 26 depends from claim 23 and thereby includes all of its limitations. In a substantially similar manner, Lieber teaches away from the proposed combination because Lieber advises using a balloon-tipped catheter having an inflated balloon propelled from the right atrium into the pulmonary artery as opposed to the alternate structure recited in claims 28, 59 and 65 (See Response to the Final Office Action dated December 5, 2005 at page 14, second paragraph to page 15, first full paragraph), and incorporated in dependent claims 29, 33, 60-64 and 66-68.

Further still, Applicant traverses the statement in the Advisory Action at page 2, “a reference which teaches one method of maneuvering an electrode catheter does not teach away from the application of another reference that show an equally viable method of maneuvering the catheter.” Lieber provides an entirely different mechanism for maneuvering its catheter than Maseda, and when Lieber is properly considered as a whole, leads away from the claimed invention, as described above. Additionally, Applicant traverses the Advisory Action statement at page 2, “the teachings of Maseda are clearly generic to any medical device requiring controlled placement within the body,” in so far as Maseda is not applicable to references, such as Lieber, that teach a contrary mechanism for maneuvering that teaches away from the claimed invention, as described above. Because Lieber teaches away from the proposed combination and because combining Maseda with Lieber would change the principle of operation for Lieber, as described above, Applicant respectfully submits it is not obvious to combine Lieber with Maseda in the manner proposed.

Furthermore, the Final Office Action does not state how Maseda would be in need of, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claims 9, 23, 28, 59 and 65 and incorporated in dependent claims 10, 12-14, 16, 21, 22, 26, 29, 33, 58, 60-64 and 66-68. Applicant cannot find any *objective suggestion* in Maseda to employ such structure.

Additionally, the rejections fail because the rejections do not consider the claims as a whole. Instead, the Final Office Action seizes upon the differences of the claims and argues the differences would be obvious instead of considering the claims as a whole. For example, the Final Office Action at page 3, last paragraph states, “Lieber et al., however, do not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. Maseda, however, teach that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous.” As described above, the Final Office Action fails to maintain a proper *prima facie* case

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showing the new combinations of elements provided in claims 9, 23, 28, 59 and 65. Instead, the Final Office Action uses Applicants' disclosure as a template and performs improper hindsight reconstruction to selectively choose elements from the cited references in the proposed manner. Because the rejections focus upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established.

Conclusion

The Final Office Action fails to establish a legally sufficient case of anticipation or obviousness and Applicant traverses on several grounds as described in detail above. Applicant submits Maseda does not identically teach all of the elements. Further, Applicant submits the Final Office Action fails to maintain a *prima facie* case of obviousness because combining Maseda with Lieber would change the principle of operation of Lieber. Furthermore, Lieber teaches away from the proposed combination. Additionally, the Final Office Action selectively combines the Maseda and Lieber references without the required objective reasoning and without considering the claims as a whole. Applicant respectfully submits the Advisory Action fails to remedy the deficiency of motivation to combine Maseda with Lieber in the manner proposed.

In light of the above, Applicant submits that when properly considered as a whole, and when the actual claim language is examined without hindsight reconstruction, the pending claims are patentable over the cited art. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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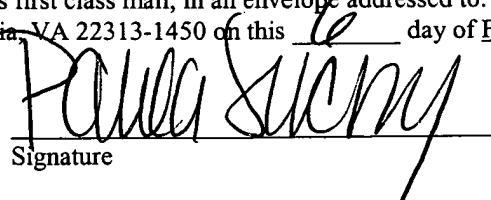
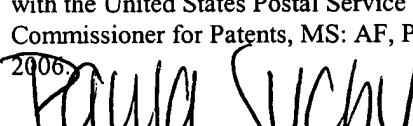
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